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EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,896	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,25 and 26* is/are rejected.

7)☒ Claim(s) *15,23 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 15 is objected to because of the following informalities:

Claim 15 appears to contain a typographical error. It reads the phrase "of at any time" in line 2. Appropriate correction is required.

Claims 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 7-9, 11-15 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 6,004,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method of increasing weight in poultry using an animal supplement comprising animal plasma. Therefore the claims of '576 anticipate the instant claims.

The methods of claims 1-4 and 6-8 of '576 encompass methods of increasing weight gain of an animal comprising administering to animals a supplement comprising spray dried animal plasma wherein the plasma is formed into particles ranging in size of 100-2000 microns. Claims 1-4 and 6-8 of '576 anticipate claims 1-4 and 7-9 of the instant invention as they are drawn to methods of increasing live weight of poultry, which is an animal, by supplementing feed with spray dried animal plasma wherein the particle size of the animal plasma is between 50 and 2000 microns (claims 1-4 and 7-9). While claim 1 of '576 is drawn to increasing the weight of any species of animal, claim 7 of '576 limits the animal species to those including chicken, duck and turkey, which are poultry as claimed in claim 14 of the instant invention. '576 claims also limit the animal plasma to 0-15% of animal rations (claim 3) which is "up to 15% by weight" as specified by claim 3 of the instant invention . Claim 8 of '576 specifies that the dried animal plasma is isolated from a number of species including porcine and bovine which are livestock as claimed in claims 11 and 12 of the instant invention. Claim 4 of '576 specifies administering the supplement in the first 10 weeks of life, which constitutes newly hatched poultry as in claim 14 of the instant invention.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the live weight of poultry comprising

administering to a poultry a supplement comprising animal plasma wherein the source of the plasma is the blood of an animal, does not reasonably provide enablement for animal plasma wherein the source is a recombinant means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches preparing a plasma product from animal blood (page 5, lines 6-30). The specification provides prophetic teaching with respect to collecting plasma proteins from recombinant transgenic animals or microorganisms (page 5, lines 3-4).

Claim 10 is directed to a method of increasing the live weight of poultry by administering animal plasma to the poultry wherein the source of the animal plasma is made through a recombinant means.

Claim 10 encompasses producing animal plasma using transformed microorganisms, a transgenic animal or a transgenic plant. The specification teaches recovering animal plasma from animal blood. The specification does not teach how to make animal plasma using microorganisms, transgenic animals or transgenic plants. With respect to microorganisms and transgenic plants, these organisms do not contain blood from which to isolate plasma. The specification does not provide any guidance with respect to how to make microorganisms or plants such that they produce plasma or blood. The specification teaches the chemical composition of animal plasma (page 6) but fails to provide any guidance with respect to what components of plasma one could make using microorganisms or transgenic plants that would be useful in the claimed method of increasing the live weight of poultry. With respect to transgenic animals, these animals do contain blood from which plasma can be isolated for use in the

claimed method. However, the specification has not provided any guidance with respect to a transgene that would alter animal plasma in a manner to cause a growth benefit over plasma isolated from a non-transgenic animal.

The state of the art at the time of filing with respect to transgenic animals was such that one of skill could not predict the phenotype of transgenics. The species-specific requirements for transgene design are not clearly understood. Examples in the literature aptly demonstrate that even closely related species carrying the same transgene construct can exhibit widely varying phenotypes. For example, several animal models of human diseases have relied on transgenic rats when the development of mouse models was not feasible. Mullins (1990, Nature, Vol. 344, 541-544) produced outbred Sprague-Dawley x WKY rats with hypertension caused by expression of a mouse *Ren-2* renin transgene. Hammer (1990, Cell, Vol. 63, 1099-1112) describes spontaneous inflammatory disease in inbred Fischer and Lewis rats expressing human class I major histocompatibility allele HLA-B27 and human β_2-microglobulin transgenes. Both investigations were preceded by the failure to develop human disease-like symptoms in transgenic mice (Mullins, 1989, EMBO J., vol. 8, pages 4065-4072; Taurog, 1988, Jour. Immunol., Vol. 141, pages 4020-4023) expressing the same transgenes that successfully caused the desired symptoms in transgenic rats. Thus, the combination of elements (protein, promoter, species of protein, and species of transgenic) required to obtain a desired effect were not within the realm of routine experimentation at the time of filing.

Not only is the difference in transgenic mice and rats unpredictable for reasons stated above, the art at the time of filing was such that a number of significant limitations regarding the production of non-human transgenic animals existed. Wall (1996, Theriogenology, Vol. 45,

pages 57-68) disclosed the unpredictability of transgene behavior due to factors such as position effect and unidentified control elements resulting in a lack of transgene expression or variable expression (paragraph bridging pages 61-62). Overbeek (1994, "Factors affecting transgenic animal production," Transgenic animal technology, pages 96-98) taught that within one litter of transgenic mice, considerable variation in the level of transgene expression occurs between founder animals and causes different phenotypes (page 96, last paragraph). Therefore, it was unpredictable at the time of filing what gene of interest, promoter, enhancer, coding, or non-coding sequences present in the transgene construct, site of integration, method used and phenotype obtained were required to make a transgenic non-human mammal of interest.

In light of the breath of the claims with respect to generating animal plasma in a microorganism or transgenic plant, in light of the unpredictability set forth by the art for making transgenics, and the lack of guidance in the specification with respect to making plasma in a microorganism or plant, it would require undue experimentation to determine how to increase the live weight of poultry by administering animal plasma from a transformed microorganism, a transgenic animal or a transgenic plant.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "supplement" in claim 1 is unclear. It is unclear what the claimed supplement is supplementing. For example, it could be a dietary supplement or a supplement to something else. Claims 2-17 depend from claim 1.

Claim 2 recites the limitation "the animals' feed" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The term "production cycle" in line 2 of claim 15 renders the claim unclear. It is not clear if the claim is referring to the life cycle, a reproductive cycle, a production cycle of a farmer or some other kind of cycle. The specification does not define the "production cycle".

The term "preferentially" renders claim 16 unclear. It is not clear what the term "preferential" is relative to. A preferential increase means there should be a corresponding decrease or a greater increase in one area, in this case it is the yield of white meat, than in another area, for example, the yield of dark meat. Claim 17 depends from claim 16.

The term "poultry feed" in claim 18 is unclear. The term is not defined in the specification and is vague. It is not clear what "poultry feed" encompasses. For the purposes of examination, "poultry feed" is defined as any food product that can be fed to poultry and is not limited to any specific type of feed. Claims 19-21 depend from claim 18.

The term "up to 100%" in claim 19 renders the claim indefinite. It is not clear if the claim encompasses 100% or any amount up to, but not including 100%.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,7-9,11-15,18-22,25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver (US 6,004,576, 1999).

Claim 1 is drawn to a method of increasing the live weight of poultry comprising administering to poultry a supplement comprising animal plasma. Claim 2 includes the limitation that the supplement be added to feed. Claim 3 requires that the supplement comprise up to 15% by weight of the animal's feed. Claims also limit the animal plasma to being spray-dried (claim 7), having a particle size of at least 50 microns (claim 8) and less than 2000 microns (claim 9). Claims 11 and 12 add the limitation that the source of the animal plasma is a livestock animal. Claim 13 limits the poultry species of claim 1. Claim 14 limits the supplement to being administered to newly hatched poultry and claim 15 limits the supplement to being administered at any time in the production cycle. Claims 18 and 19 are directed to a feed product comprising poultry feed and animal plasma wherein the animal plasma is dried (claim 20) and granulated or powdered (claim 21). Claims 4,22,25 and 26 limit the supplement used in the methods (claim 4) and products (claims 22-26) to animal serum mixed with water.

Weaver taught increasing the growth of animals, including poultry, by adding granulated animal plasma from livestock animals (column 4, lines 12-16) to other feed ingredients (column 4, lines 4-16; claim 1) to 0 to 15% by weight of the base feed (column 5, line 19) beginning at birth (column 7, line 11; claim 4). Weaver taught spray drying the plasma (column 4, lines 44-45) and compressing it into a resulting granule particle size of at least 50 microns but less than

2000 microns (column 4, lines 55-59). Because water is a feed product that is fed to poultry, the teachings of Weaver include the addition of the animal plasma to water.

Thus, the teachings of Weaver anticipate all of the claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7,11,13-15,18-22,25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adalsteinsson (US 6,086,878, effective filing date August 21, 1997).

Claim 1 is drawn to a method of increasing the live weight of poultry comprising administering to poultry a supplement comprising animal plasma. Claim 2 includes the limitation that the supplement be added to feed. Claim 3 requires that the supplement comprise up to 15% by weight of the animal's feed. Claim 11 adds the limitation that the source of the animal plasma is a livestock animal. Claim 13 limits the poultry species. Claim 14 limits the supplement to being administered to newly hatched poultry and claim 15 limits the supplement to being administered at any time in the production cycle. Claims 18 and 19 are directed to a feed product comprising poultry feed and animal plasma wherein the animal plasma is dried (claim 20) and granulated or powdered (claim 21). Claims 4,22,25 and 26 limit the supplement used in the methods (claim 4) and products (claims 22-26) to animal serum mixed with water.

Adalsteinsson taught administering spray dried egg yolk to newly hatched chickens as a feed supplement for the purpose of increasing muscle mass (column 12, lines 6-16). The egg yolk was from eggs of chickens that had been immunized with CCK antigen (column 11, lines 30-53). Adalsteinsson taught the source of the antibodies can be egg yolk or blood plasma of the target animal, which was a chicken (column 8, line 65) and is a livestock animal as claimed in claim 11. The supplement was added to poultry feed at 50-500 grams per ton, which is up to 15% by weight (claim 3), and up to 100% by weight (claim 19). Adalsteinsson also taught mixing spray-dried egg yolk in drinks. Because water is a drink that is fed to poultry, the teachings of Adalsteinsson include the addition of the spray dried egg yolk to water (column 9, lines 47-49).

The exemplifications of Adalsteinsson differ from the claimed invention in that Adalsteinsson did not exemplify using spray dried animal plasma as an antibody source.

However, Adalsteinsson had taught that antibodies beneficial to the growth of an animal could be obtained from other sources such as animal plasma (column 2, lines 6-8; column 7, lines 39-41; column 8, lines 60-65).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to administer a supplement containing antibodies as exemplified by Adalsteinsson wherein the source of the antibodies was spray dried animal plasma as taught by Adalsteinsson. One of ordinary skill in the art at the time the invention was made would have been motivated to use spray dried animal plasma as a source of antibodies in a feed supplement because Adalsteinsson taught that animal plasma is a source of antibodies that can treat infectious diseases and increase meat yield in animals (column 2, lines 17-26 and 36-61).

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Fri 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PETER PARAS, JR.
PRIMARY EXAMINER

Valarie Bertoglio
Examiner
Art Unit 1632